

## RANDOMIZED TRIAL

## Effectiveness of Rocker Sole Shoes in the Management of Chronic Low Back Pain

*A Randomized Clinical Trial*Catharine Siân MacRae, PhD,\* Jeremy S. Lewis, PhD,†‡§ Adam P. Shortland, PhD,¶||  
Matthew C. Morrissey, ScD,\*\*†† and Duncan Critchley, PhD‡‡**Study Design.** Multicenter, assessor-blind, randomized, clinical trial.**Objective.** To compare the effectiveness of rocker sole footwear to traditional flat sole footwear as part of the management for people with low back pain (LBP).**Summary of Background Data.** During the past decade, persistent advertising has claimed that footwear constructed with a rocker sole will reduce LBP. However, there is no robust evidence to support these claims.**Methods.** One hundred fifteen people with chronic LBP were randomized to wear rocker sole shoes or flat sole shoes for a minimum of 2 hours each day while standing and walking. Primary outcome was the Roland Morris Disability Questionnaire (RMDQ). In addition, participants attended an exercise and education program once a week for 4 weeks and wore their assigned shoes during these sessions. Participants were assessed without their knowledge of group allocation prerandomization, and at 6 weeks, 6 months, and 1 year (main outcome point). Analysis was by intention-to-treat method.**Results.** At 12 months, data from 44 of 58 (77.2%) of the rocker sole group and 49 of 57 (84.5%) of the flat sole group were available for analysis. In the rocker sole group, mean reduction in RMDQ was  $-3.1$  (95% CI [confidence interval],  $-4.5$  to  $-1.6$ ), and in the flat sole group, it was  $-4.4$  (95% CI,  $-5.8$  to  $-3.1$ ) (a greater negative value represents a greater reduction in disability). At 6 months, more people wearing flat shoes compared with those wearing rocker shoes demonstrated a minimal clinically important improvement in disability (53.2% and 31.1%, respectively;  $P = 0.03$ ). Between-group differences were not significant for RMDQ or any secondary outcomes (e.g., pain) at any time. People reporting pain when standing and walking at baseline ( $n = 59$ ) reported a greater reduction in RMDQ at 12 months in the flat sole group ( $-4.4$  [95% CI,  $-6.0$  to  $-2.8$ ],  $n = 29$ ) than the rocker sole group ( $-2.0$  [95% CI,  $-3.6$  to  $-0.4$ ],  $n = 30$ ) ( $P < 0.05$ ).**Conclusion.** Rocker sole shoes seem to be no more beneficial than flat sole shoes in affecting disability and pain outcomes in people with chronic LBP. Flat shoes are more beneficial for LBP aggravated by standing or walking.**Key words:** low back pain, rehabilitation, exercise, rocker sole shoes, footwear.**Level of Evidence:** N/A**Spine 2013;38:1905-1912**

From the \*Therapy Department, Chelsea and Westminster Hospital NHS Foundation Trust, London, United Kingdom; †Department of Allied Health Professions, School of Health and Social Work, University of Hertfordshire, Hatfield, United Kingdom; ‡Musculoskeletal Services, Central London Community Healthcare NHS Trust, London, United Kingdom; §Therapy Department, St George's Hospital NHS Trust, London, United Kingdom; ¶Imaging Sciences and Biomedical Engineering, King's College London, London, United Kingdom; ||One Small Step Gait Laboratory, Guy's and St Thomas' NHS Foundation Trust, King's Health Partners, London, United Kingdom; \*\*Department of Physical Therapy, University of St Augustine for Health Sciences, Austin, TX; ††Faculty of Health Sciences, University of Ljubljana, Slovenia; and ‡‡Division of Health and Social Care Research, School of Medicine, King's College London, London, United Kingdom.

Acknowledgment date: February 15, 2013. First revision date: June 10, 2013. Second revision date: July 5, 2013, Acceptance date: July 8, 2013.

The manuscript submitted does not contain information about medical device(s)/drug(s).

Masai GB Ltd. grant funds were received in support of this work.

No relevant financial activities outside the submitted work.

Address correspondence and reprint requests to Catharine Siân MacRae, PhD, Physiotherapy Department, Chelsea and Westminster Hospital, 369 Fulham Road, London, SW10 9NH; E-mail: sianmacrae@nhs.net

DOI: 10.1097/BRS.0b013e3182a69956

Low back pain (LBP) is common with a lifetime incidence of up to 80%<sup>1,2</sup>; 5% to 20% develop more persistent chronic low back pain (CLBP).<sup>3-6</sup> Health care costs are consequently substantial.<sup>7-9</sup>

Although national<sup>10</sup> and international guidelines<sup>11</sup> recommend exercise therapy in the management of CLBP, the long-term effectiveness of such an approach seems minimal.<sup>12,13</sup> The equivocal nature of research may be due to patient heterogeneity. CLBP may represent different subgroups that may respond differently to different treatments.<sup>14,15</sup> Assessing these subgroups together as one homogeneous group may dilute specific treatment effects, hence explaining the minimal observed benefit of exercise in clinical trials. Consequently, novel approaches yet to be investigated in robust randomized controlled trials have been proposed<sup>16,17</sup> as alternatives and possibly effective adjuncts to LBP management.

Rocker sole footwear have been marketed with persuasive advertising suggesting that use of this footwear leads to a reduction in LBP.<sup>18</sup> Manufacturers claim that the unstable curved sole can positively influence mechanisms associated with CLBP, such as poor balance, substandard muscle function, poor posture, and reduced capacity to attenuate shock while walking.<sup>17</sup> However, there is no evidence in the literature supporting these claims.

The primary aim of this randomized clinical trial was to assess whether wearing rocker sole shoes would result in an improvement in disability and reduction in pain when compared with wearing flat sole shoes during a typical exercise treatment for CLBP. The primary hypothesis being that the addition of rocker sole shoes to the treatment of CLBP will result in a significant reduction in disability (Roland Morris Disability Questionnaire [RMDQ]) in patients with CLBP when compared with the addition of flat sole shoes when assessed at 6 weeks, 6 months, and 1 year (primary end point). A secondary aim was to determine whether people whose LBP was aggravated predominately through standing or walking would gain a greater reduction in disability if they wore rocker sole shoes than flat sole shoes. The secondary hypothesis states that, for the subgroup of people reporting pain while standing or walking, there will be a better outcome for disability in people wearing rocker sole shoes than those wearing flat sole shoes at 6 weeks, 6 months, and 1 year.

## MATERIALS AND METHODS

### Design

This was a multicenter, assessor-blind, randomized, clinical trial conducted through 4 publicly funded secondary care hospital physiotherapy departments and one private physiotherapy department in London, the United Kingdom.

### Participant Recruitment

Ethical approval was obtained from the Riverside Research Ethics Committee (09/H0706/4). One hundred fifteen participants with CLBP referred from general practitioners and consultants were recruited. Eligible participants were aged 18 to 65 years with a 3-month or greater history of LBP. Exclusion criteria were constant LBP; specific spinal medical diagnosis inappropriate for physiotherapy interventions, for example spinal fracture or infection; inappropriate to wear rocker sole shoes in accordance with footwear company (Masai GB Limited, London, United Kingdom) recommendations, for example peripheral neuropathy, history of falls, Morton neuroma; inappropriate for exercise physiotherapy, for example severe cardiovascular or metabolic disease preventing participation in the exercise group; participants who had previously used rocker sole shoes.

### Consent and Randomization

Study participants provided informed consent prior to entry into the study and were assigned by block randomization (blocks of 4) into their allocated group. The chief investigator remained blind to group allocation for the duration of the

study. Five separate randomization sheets, one for each site, each with a total of 60 potential participant group allocations (15 blocks of 4, randomly selected by M.M.) were produced and stored on a password-protected computer at each site.

### Interventions

Participants were given either a pair of rocker sole shoes (Masai Barefoot Technology [MBT] Chapa Caviar, Masai GB Limited, London, United Kingdom) or flat sole shoes (Gel 1140, ASICS, Warrington, United Kingdom) (Figure 1). Company logos were removed from both shoe types. Coresearchers at each site (trained by a representative from MBT GB Ltd in correct rocker sole shoe fitting and walking techniques) fitted participants with their allocated footwear and educated participants on correct standing and walking technique for their allocated footwear (approximately 30-minute duration). The same amount of time was spent to train the flat sole shoe wearers to wear their allocated shoes.

To reduce the occurrence of ailments associated with wearing a new pair of shoes, for example blisters, participants were instructed to increase the time gradually for which study shoes were worn each day, initially from 15 to 30 minutes, progressing to a minimum wear of 2 hours per day while standing and walking by the end of the first week. Participants were instructed to wear their assigned shoes for periods of time totaling a minimum of 2 hours every day, for the duration of the follow-up period (1 yr).

One week after getting accustomed to the footwear, participants attended the LBP exercise group. The exercise group (a recommended treatment for patients with CLBP<sup>10,19</sup>) lasted approximately for a duration of 1 hour, once a week, for 4 weeks. The exercise program involved a 5-minute warm up, 10 exercises (see Supplemental Digital Content Appendix, available at <http://links.lww.com/BRS/A809>), a 5-minute cool down and a 10-minute education session ("Managing a flare up," "Pain," "Exercise," and "Relaxation"<sup>20</sup>). The exercises were standardized across the 5 sites. Exercises were chosen



Figure 1. Rocker sole shoe (bottom) and flat sole shoe (top).

according to research recommendations for the management of CLBP,<sup>10,21</sup> while considering available space, equipment, and class duration time at each site. The exercises aimed to improve the strength of limb and trunk muscles and increase cardiovascular fitness, in addition to specific trunk muscle exercises. Study participants wore their study shoes during the exercise group.

### Outcomes

Participants were assessed at baseline, 6 weeks, 6 months, and 1 year. Outcome measures completed at baseline were the RMDQ<sup>22</sup> (primary outcome), Numerical Rating Scale for pain,<sup>23</sup> EQ-5D-3L Health Questionnaire (a measure of health-related quality of life),<sup>24</sup> Tampa Scale of Kinesiophobia<sup>25</sup> (fear avoidance questionnaire), Hospital Anxiety and Depression Questionnaire,<sup>26</sup> and Patient-Specific Functional Scale.<sup>27</sup> In addition, at 6 weeks, participants reported the time spent per day in the study shoes (this was recorded daily by each participant from baseline to 6-week assessment in a diary),

and at 6 months and 1 year (primary outcome point), participants additionally reported the number of days taken off work because of LBP in the past 6 months, and satisfaction with their study shoes.<sup>28</sup>

### Sample Size Calculation

For a power of 0.9 and an  $\alpha$  of 0.01 based on a standard deviation of 5 (pilot study data from 20 participants) and an ability to detect a 4-point change in the mean RMDQ scores between baseline and reassessment,<sup>29</sup> the number of participants needed for each of the groups equaled 47. This was increased to 60 for an anticipated 20% participant loss to follow-up and missing data. Therefore, it was anticipated that 120 participants were required.

### Adverse Events

Adverse events were defined as an increase in pain or symptoms within 1 week of commencing an intervention requiring general practitioner or casualty consultation.<sup>30</sup>

**TABLE 1. Baseline Characteristics of the Study Participants**

	Flat Sole Shoe Group (n = 58)	Rocker Sole Shoe Group (n = 57)	P
Sex			
Male	19 (33)*	20 (35)*	0.79†
Female	39 (67)*	37 (65)*	
Age (yr)	43.0 (12.1)	43.1 (12.1)	0.98
Body mass (kg)	75.7 (14.0)	74.3 (14.7)	0.38
Body height (cm)	170 (7)	169 (10)	0.61
Body mass index (kg/m <sup>2</sup> )	26.2 (4.6)	25.7 (4.7)	0.53
Time since first episode of LBP (yr)	7.9 (9.0)	7.0 (7.9)	0.57
Disability (Roland Morris Disability Questionnaire) (0–24; 0 = best)	9.2 (4.7)	7.8 (5.0)	0.13
Pain (Numerical Rating Scale) (0–10; 0 = best)	6.6 (2.0)	6.6 (1.7)	0.91
Quality of life (EQ-5D VAS) (0–100; 100 = best)	68 (17)	63 (19)	0.13
Quality of life (EQ-5D) (–0.5 to 1.0; 1 = best)	0.7 (0.2)	0.6 (0.2)	0.10
Fear avoidance (Tampa Scale of Kinesiophobia) (17–68; 17 = best)	38.4 (6.5)	38.4 (6.1)	0.64
Anxiety (Hospital Anxiety and Depression Scale) (0–21; 0 = best)	7.7 (3.6)	7.5 (4.2)	0.33
Depression (Hospital Anxiety and Depression Scale) (0–21; 0 = best)	5.2 (3.1)	4.8 (3.7)	0.22
Function (Patient-Specific Functional Scale) (0–10; 10 = best)	4.5 (1.7)	4.3 (1.8)	0.46
Pain while standing or walking‡ (number of participants)	30 (51.7)*	29 (50.9)*	0.93†
Summary measures represent means (SD), or *number (%). P values determined from independent t test, or † $\chi^2$ test. ‡As reported on the Patient-Specific Functional Scale.			

## Statistical Analysis

The primary analysis was by intention-to-treat method, including all eligible randomized participants who provided follow-up data. Two-way mixed model (between-within) analysis of variances were conducted with one within-subject factor (assessment time points) and one between-group factor (footwear type) to compare the effectiveness of footwear type over time. Analysis of variance used data from participants with complete data sets for all 4 time points (rocker sole shoe group  $n = 40$ , flat sole shoe group  $n = 43$ ) unless otherwise stated. A sensitivity analysis used “expectation-maximization” to impute missing values. Analysis of covariance, with baseline data for the primary outcome (RMDQ) from each group as the covariate, compared the effects of treatment at each reassessment point. A  $\chi^2$  test assessed differences between the groups regarding numbers reporting minimal clinically important differences in disability (greater than or equal to a 4-point improvement in the RMDQ<sup>29</sup>).

One preplanned subgroup analysis was conducted. Data from participants reporting pain aggravated by standing or walking on the Patient-Specific Functional Scale at baseline were analyzed using 2-way mixed model analysis of variance, to determine whether shoe allocation influenced disability in this subgroup. Data were analyzed using IBM SPSS version 20.0.0 (IBM, Armonk, New York). Results are presented as means (standard deviations) unless otherwise stated.

## RESULTS

One hundred fifteen participants were recruited into the study from April 2009 to November 2010. There were no differences between the groups in demographic data or outcome measures (Table 1) at baseline; however, there was a tendency toward an increased disability (RMDQ) in the flat sole shoe group.

Participant attrition and retention during the study are presented in Figure 2. At 12 months, 93 (81%) participants were reassessed. There was no difference between the groups in retention at 12 months.

Both groups reported reductions in disability at each time point when compared with baseline ( $P < 0.01$  flat sole group,  $P < 0.001$  rocker sole group) (Table 2; Figure 3). There were no differences between the groups at any follow-up point.

Disability was not different between the groups at any time point, taking into account baseline disability (analysis of covariance) ( $P = 0.58$ ) or after missing number imputation ( $P = 0.13$ ).

A greater proportion of participants allocated to wear flat sole shoes (53%) than those allocated to the rocker sole group (31%) reported a minimal clinically important improvement at 6 months ( $P = 0.03$ ). There were no differences between the groups at 6 weeks ( $P = 0.56$ ) or 12 months ( $P = 0.24$ ).

Flat sole shoe wearers in the subgroup reporting pain while standing and walking showed a greater improvement in disability than the rocker sole shoe wearers at 6 weeks ( $-3.2$  [ $-4.5$  to  $-2.0$ ] and  $-1.2$  [ $-2.3$  to  $-0.2$ ], respectively;  $P = 0.02$ ) and 12 months ( $-4.4$  [ $-6.0$  to  $-2.8$ ] and  $-2.0$  [ $-3.6$

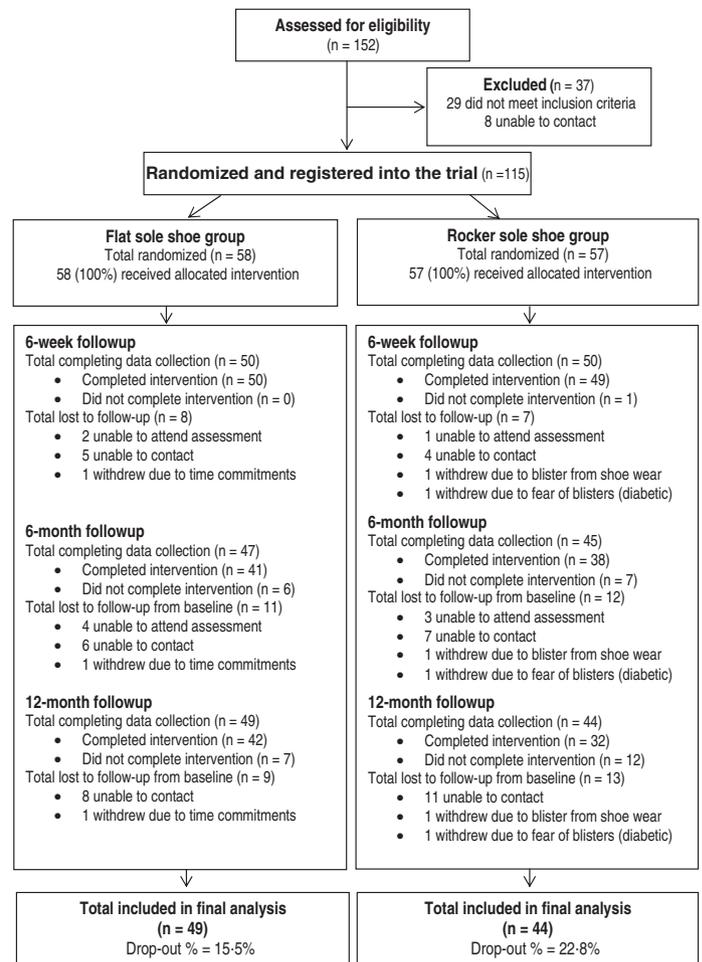


Figure 2. Flow of participants through trial.

to  $-0.4$ ], respectively;  $P = 0.04$ ) (Figure 4). There was no between-group difference at any time point in the subgroup of participants who did not report pain while standing and walking ( $P = 0.48$ ).

Both groups reported reductions in their Numerical Rating Scale for pain intensity at each time point when compared with baseline ( $P < 0.01$ ). At 12 months, the flat sole group demonstrated a 2.7-point reduction (SD, 2.7), and the rocker sole group demonstrated a 2.3-point reduction (SD, 2.8) in Numerical Rating Scale for pain. There were no differences between the groups for secondary outcomes investigating fear of movement, spinal impairment, days off work, health-related quality of life, patient-specific functional activity, and anxiety and depression, when compared at any follow-up point (Table 2).

At 6 and 12 months, participants in the flat sole shoe group were more satisfied with the shoe they received than participants in the rocker sole shoe group (at 6 mo, 62% and 37%, respectively;  $P = 0.02$ ) and at 12 mo, 73% and 46%, respectively;  $P = 0.01$ ) were very or extremely satisfied). No significant differences between the groups at the 3 reassessment points were noted for reported adherence to shoe use protocol.

**TABLE 2. Outcome Measures During the Course of the Trial**

Outcome Measure	Intervention Group	
	Flat Sole Shoe	Rocker Sole Shoe
Disability (Roland Morris Disability Questionnaire, 0–24; 0 = best) (points)		
Baseline	9.2 (7.8–10.6)	7.1 (5.6–8.5)
6 wk	6.1 (4.9–7.2)	4.9 (3.4–6.3)
6 mo	5.3 (3.8–6.7)	4.8 (3.3–6.2)
12 mo	4.8 (3.4–6.1)	4.0 (2.5–5.6)
Pain (Numerical Rating Scale, 0–10; 0 = best) (points)		
Baseline	6.9 (6.3–7.5)	6.4 (6.0–6.9)
6 wk	4.9 (4.3–5.5)	4.6 (3.9–5.4)
6 mo	4.3 (3.5–5.0)	4.0 (3.2–4.8)
12 mo	4.2 (3.4–5.0)	4.2 (3.2–5.1)
Function (Patient-Specific Functional Scale score, 0–10; 10 = best) (points)		
Baseline	4.3 (3.8–4.8)	4.4 (3.8–5.0)
6 wk	6.1 (5.6–6.7)	5.8 (5.2–6.5)
6 mo	6.7 (6.1–7.3)	6.4 (5.8–7.1)
12 mo	7.1 (6.4–7.7)	6.7 (6.1–7.4)
Quality of Life (EQ-5D-3L, –0.5 to 1.0; 1 = best)		
Baseline	0.7 (0.6–0.7)	0.6 (0.6–0.7)
6 wk	0.7 (0.7–0.8)	0.6 (0.6–0.7)
6 mo	0.7 (0.7–0.8)	0.7 (0.7–0.7)
12 mo	0.8 (0.7–0.8)	0.7 (0.6–0.8)
Visual Analogue Scale for Quality of Life (EQ-5D-3L, 0–100; 100 = best) (points)		
Baseline	70.0 (65.6–74.5)	64.4 (58.2–70.5)
6 wk	72.1 (67.1–77.0)	69.1 (62.5–75.8)
6 mo	72.0 (66.4–77.6)	66.9 (60.7–73.1)
12 mo	75.6 (71.0–80.3)	70.5 (63.3–77.6)
Fear avoidance (Tampa Scale of Kinesiophobia, 17–68; 17 = best) (points)		
Baseline	37.9 (36.0–39.8)	36.2 (34.4–37.9)
6 wk	36.8 (34.9–38.6)	34.7 (32.5–36.9)
6 mo	37.1 (34.8–39.4)	34.7 (32.1–37.3)
12 mo	34.7 (32.0–37.4)	34.3 (31.8–36.7)
Anxiety (Hospital Anxiety and Depression Scale, 0–21; 0 = best) (points)		
Baseline	7.3 (6.2–8.4)	6.9 (5.4–8.4)
6 wk	6.1 (5.1–7.1)	7.4 (5.7–9.0)

(Continued)

**TABLE 2. (Continued)**

Outcome Measure	Intervention Group	
	Flat Sole Shoe	Rocker Sole Shoe
6 mo	6.9 (5.8–7.9)	7.2 (5.4–9.0)
12 mo	6.0 (4.9–7.1)	6.3 (4.7–8.0)
Depression (Hospital Anxiety and Depression Scale, 0–21; 0 = best) (points)		
Baseline	4.7 (3.8–5.7)	4.3 (3.0–5.7)
6 wk	3.2 (2.3–4.2)	4.1 (2.6–5.7)
6 mo	4.0 (3.1–5.0)	4.2 (2.5–6.0)
12 mo	3.5 (2.7–4.4)	4.3 (2.7–5.9)
Average time study shoes worn per week (hr)		
6 wk	17.0 (13.3–20.6)	18.0 (14.8–21.2)
6 mo	15.0 (10.6–19.4)	14.0 (9.9–18.0)
12 mo	14.4 (10.3–18.6)	11.9 (7.5–16.4)
Satisfaction (global satisfaction score)*		
6 mo	26/42 (62%)	16/43 (37%)†
12 mo	33/45 (73%)	17/37 (46%)†
Time off work due to low back pain (d)		
6 mo	1.7 (6.5)	0.5 (1.6)
12 mo	1.5 (6.2)	0.7 (2.8)
Adherence to shoe use protocol‡		
6 wk	22/42 (52%)	24/40 (60%)
6 mo	16/46 (35%)	23/44 (52%)
12 mo	20/48 (42%)	14/43 (33%)

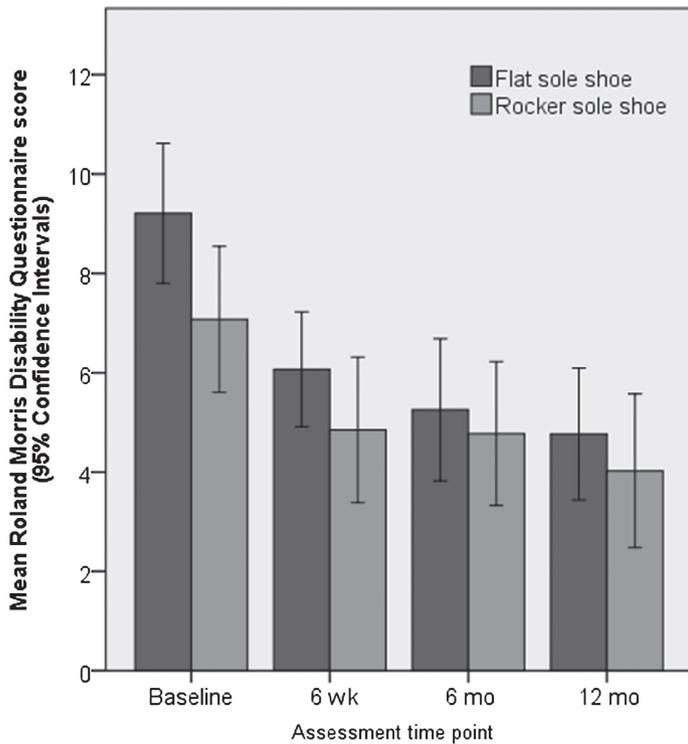
Summary measures are means (95% confidence intervals).  
 \*Global satisfaction scores represent number (%) of participants “very” or “extremely” satisfied.  
 †Significant difference between the groups at  $P < 0.05$ .  
 ‡Adherence to shoe use protocol: number (%) of participants wearing their shoes for an average of 2 or more hours per day calculated from diary sheets or reported weekly averages.

**Adverse Events**

No serious adverse events were reported. In the rocker sole shoe group, one participant withdrew from the study in the first week because of blister formation, and one participant, who was diabetic, withdrew because of a fear of blister formation from the new footwear.

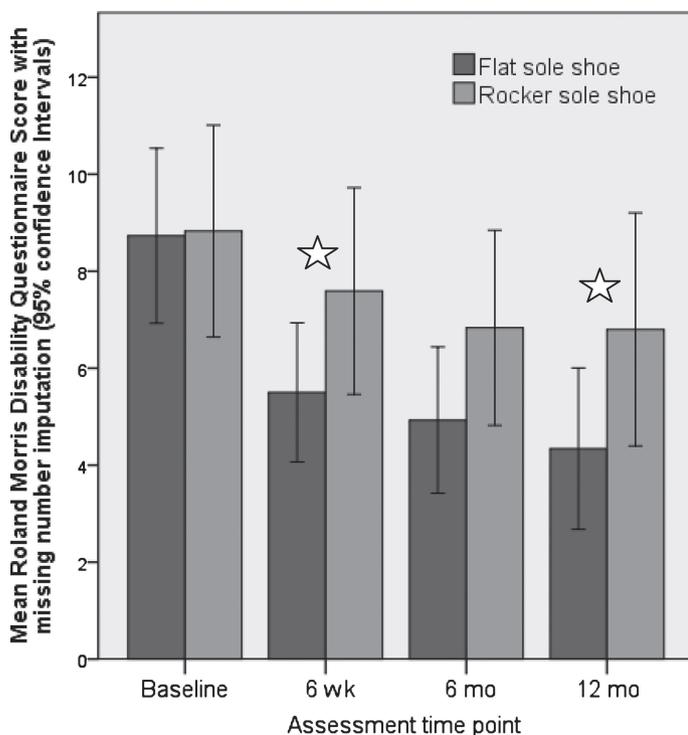
**DISCUSSION**

The results demonstrate that in a CLBP population, people who attended a 4-week exercise program and wore either flat sole or rocker sole shoes reported similar improvements in disability at 1 year when compared with baseline. A greater proportion of those in the flat sole group reported a minimal clinically important improvement in disability at 6 months



**Figure 3.** Primary outcome: Roland Morris Disability Questionnaire Scores (scale: 0–24; 0 = best).

than those wearing the rocker shoes ( $P = 0.03$ ). For those reporting pain while standing and walking, improvement in disability at 6 weeks and 12 months was greater for those in



**Figure 4.** Change in disability score from baseline for those reporting pain while standing or walking.

the flat sole than in the rocker sole group ( $P = 0.02$  and  $P = 0.04$ , respectively). At both 6 months and 12 months, participants in the flat sole group were more satisfied than the participants in the rocker sole group with the shoe they received ( $P = 0.02$  and  $P = 0.01$ , respectively).

The only published randomized controlled trial investigating rocker sole footwear in LBP<sup>31</sup> reported a nonclinically important reduction in pain in male golfers at 6 weeks compared with those who wore normal footwear. This finding concurs with the absence of clinical improvement in pain in this study in either group at 6 weeks.

While standing, individuals with CLBP demonstrate greater postural instability than people without,<sup>32–34</sup> suggesting that, if a cause-effect relationship exists, reducing this postural instability may reduce LBP and associated disability. Rehabilitation of postural instability with proprioceptive or balance training has been shown to be a successful treatment in other regions of the body.<sup>35,36</sup> Although rocker sole shoes have been suggested to reduce postural instability,<sup>37</sup> this research indicates that for those reporting LBP while standing and walking, the use of rocker sole shoes, introducing additional postural instability, results in a poorer recovery than when flat sole shoes are worn. In this subgroup, reporting LBP while standing and walking, the use of rocker shoes may present too great a challenge to the postural control system. The presence of pain has been associated with inhibition and delayed contraction of trunk muscles,<sup>38,39</sup> and may detrimentally affect the initiation of appropriate balance strategies.<sup>33</sup> For the subgroup analyzed, the addition of an unstable standing surface to a pre-existing inefficient postural control system<sup>32–34</sup> may be detrimental, and account for the less good outcome observed in the rocker sole group.

Though not significantly different, baseline mean disability was lower in the rocker sole than the flat sole group. However, when taking into account the effect of baseline disability score (analysis of covariance), differences between the groups for changes in disability between the groups at reassessment remained nonsignificant.

Although differences between the groups for the primary outcome were demonstrated for the subgroup analysis at 6 weeks and 12 months, and for minimal clinically important difference at 6 months, no between-group differences for the primary outcome were demonstrated at primary end point for the intention-to-treat analysis. It is possible that clinical differences did occur between the groups at this point, but were not detected by the primary outcome. Although the main outcome measure assessed disability, a range of recommended measures, sensitive to clinical change in CLBP<sup>40,41</sup> were additionally completed. There were no differences between the groups for any of the clinical outcome questionnaires assessed. This adds strong support to the study conclusions that clinical difference between the groups did not occur at primary end point.

People with conditions such as LBP may seek medical interventions at the peak of their symptoms,<sup>42</sup> and that natural improvement may follow. Although both groups in this study showed improvement in reported disability at 12 months,

without the presence of a control group, it is not possible to conclude whether the observed improvement resulted from the initial effects of exercise, the prolonged use of footwear, changes in psychological factors,<sup>43</sup> or natural improvement.<sup>44</sup>

The provision of footwear introduced the potential for a placebo effect<sup>45</sup> in both groups. Because of media reports and marketing relating to rocker shoes during the trial, the influence of a placebo effect may have favored those in the rocker sole group.<sup>46</sup> However, due to the lack of difference observed in this study between the groups, if a positive placebo effect did influence the rocker sole group it may have been too small to result in between-group differences or may have been negated by other variables, such as a biomechanical influence.

Results obtained from completion of the study diary sheets relied on accurate self-reporting of shoe use from participants. It is acknowledged that this method of reporting may not be accurate with a tendency to overestimate adherence by approximately 10%.<sup>47</sup> However, there does not seem to be a reason why those in the rocker sole shoe group would be more prone to inaccurate recall of such data than those in the flat sole shoe group; hence, any inaccurate reporting is unlikely to bias the results.

Although not significant, a larger proportion of participants not completing the study had been allocated to the rocker sole group. Rocker sole use may in some way be accountable for this increased drop-out rate. Two subjects allocated to the rocker sole group withdrew within the first week because of a shoe-related foot blister or the fear of getting a foot blister. Other possible explanations for the tendency to greater attrition from the rocker sole group include: difficulties adapting to walking with rocker sole shoes, impracticalities of wearing rocker sole style of shoes, and difficulties adjusting to the additional weight of the rocker sole shoes (which were approximately twice the mass of the flat sole shoes). The lower participant satisfaction scores and greater number of participants lost to follow-up in the rocker sole group suggest that the rocker sole shoes were less acceptable. Investigating the possible influence of patients' opinion or thoughts about the shoes received, in addition to patients' baseline preference of shoe design and color, may have further informed study findings.

Inclusion into the study did not depend on a set threshold score on the RMDQ (primary outcome). A minimal clinically important difference of 4 points<sup>29</sup> has been described for the RMDQ; hence, a score of 4 points or greater at baseline may have been an appropriate inclusion criteria to enable all participants the potential to demonstrate a clinically important change.

## CONCLUSION

On the basis of the findings of this randomized clinical trial, clinicians should be confident to advise patients with CLBP that wearing either rocker sole shoes or flat sole shoes may offer similar outcomes in disability and pain. However, if a patient reports LBP when standing or walking, it may be more beneficial to wear flat sole shoes than rocker sole shoes.

## ➤ Key Points

- ❑ Rocker sole shoes seem to be no more beneficial than flat sole shoes in affecting disability and pain outcomes in people with CLBP.
- ❑ If a person's CLBP is predominately aggravated by standing or walking it may be more beneficial to wear flat sole shoes than rocker sole shoes.
- ❑ A greater proportion of participants who wore the flat sole shoes reported a clinically important change in self-reported disability at 6 months.
- ❑ At both 6 months and 12 months, participants in the flat sole shoe group were more satisfied than the participants in the rocker sole shoe group with the shoe they received.

## Acknowledgments

The authors thank all participants and physiotherapists who contributed from each site, namely: M Sedaghat, T Lowry, D Earl, B Crane, R Siviter, D Burnett, C Dempster, T Donegan, D Camp, L Pymont, S Thomson, J Hawton, N Hanrahan, E Roland, T Crossley, P Sawtell, CJ Swaby. The authors also thank all physiotherapy departments who participated in this trial, namely: Balance Performance Physiotherapy, Clapham, London, United Kingdom, SW4; Chelsea and Westminster Hospital, Chelsea, London, United Kingdom, SW10; Kingston Hospital, Kingston, United Kingdom, KT2; Queen Mary's Hospital, Roehampton, United Kingdom, SW14; and St. George's Hospital, Tooting, United Kingdom SW18.

Supplemental digital content is available for this article. Direct URL citation appearing in the printed text is provided in the HTML and PDF version of this article on the journal's web site ([www.spinejournal.com](http://www.spinejournal.com)).

## References

1. Airaksinen O, Brox J, Cedraschi C, et al. Chapter 4, European guidelines for the management of chronic nonspecific low back pain. *Eur Spine J* 2006;15:s192-300.
2. Koes BW, van-Tulder MW, Thomas S. Diagnosis and treatment of low back pain. *BMJ* 2006;332:1430-34.
3. Klaber Moffett J, Chase S, Portek I, et al. A controlled, prospective study to evaluate the effectiveness of a back school in the relief of chronic low back pain. *Spine* 1986;11:120-22.
4. Johanssen F, Remvig L, Kryger P, et al. Exercise for chronic lower back pain: a clinical trial. *J Orthop Sport Phys* 1995;22:52-9.
5. Quittan M. Management of back pain: review. *Disabil Rehabil* 2002;24:423-34.
6. Tortensen T, Ljunggren A, Meen H, et al. Efficiency and costs of medical exercise therapy, conventional physiotherapy and self exercise in patients with chronic low back pain. A pragmatic, randomized, single-blinded, controlled trial with 1 year follow-up. *Spine* 1998;23:2616-24.
7. Maniadakis N, Gray A. The economic burden of back pain in the UK. *Pain* 2000;84:95-103.
8. Asche CV, Kirkness CS, McAdam-Marx C, et al. The societal costs of low back pain. *J Pain Palliat Care Pharmacother* 2007;21:25-33.
9. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. *Spine J* 2008;8:8-20.

10. NICE. Low back pain: early management of persistent non-specific low back pain (Full guideline) NICE clinical guideline 88. *Natl Inst Health Clin Excell* 2009.
11. Koes BW, van Tulder MW, Lin CW, et al. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. *Euro Spine J* 2010;19:2075–94.
12. Hayden JA, van Tulder MW, Malmivaara A, et al. Exercise therapy for treatment of non-specific low back pain. *Cochrane Database Syst Rev* 2005; CD000335.
13. UK BEAM Trial Team. United Kingdom back pain exercise and manipulation (UKBEAM) randomised trial: effectiveness of physical treatments for back pain in primary care. *BMJ* 2004;329:1377–85.
14. Wand B, O'Connell N. Chronic non-specific low back pain - sub-groups or a single mechanism? *BMC Musculoskelet Disord* 2008;9:11.
15. van Middelkoop M, Rubinstein SM, Verhagen AP, et al. Exercise therapy for chronic nonspecific low-back pain. *Best Pract Res Clin Rheumatol* 2010;24:193–204.
16. Elbaz A, Mirovsky Y, Mor A, et al. A novel biomechanical device improves gait pattern in patient with chronic nonspecific low back pain. *Spine* 2009;34:E507–12.
17. Masai Barefoot Technology GB Ltd. Masai Barefoot Technology Limited, Why MBT's keep moving. *A Selection of Studies on the Effects of MBT's on the Body. Company Manual*, London 2011.
18. Masai Barefoot Technology GB Ltd. Available at: [www.uk.mbt.com/Home/Benefits.aspx](http://www.uk.mbt.com/Home/Benefits.aspx). Accessed March 17, 2012.
19. Liddle S, Gracey J, Baxter G. Advice for the management of low back pain: a systematic review of randomised controlled trials. *Manual Ther* 2007;12:310–27.
20. Jacobsen E. *Progressive Relaxation*. Chicago, IL: University of Chicago Press; 1938.
21. McGill SM. *Low Back Disorders: Evidence-Based Prevention and Rehabilitation*. 2nd ed. Champaign, IL: Human Kinetics; 2007.
22. Roland M, Morris R. A study of the natural history of back pain - part 1: development of a reliable and sensitive measure of disability in low back pain. *Spine* 1983;8:141–50.
23. Pengel L, Refshauge K, Maher C. Responsiveness of pain, disability, and physical impairment outcomes in patients with low back pain. *Spine* 2004;29:879–83.
24. Brooks R. EuroQol: the current state of play. *Health Policy* 1996;37:53–72.
25. Woby SR, Roach NK, Urmston M, et al. Psychometric properties of the TSK-11: a shortened version of the Tampa Scale for Kinesiophobia. *Pain* 2005;117:137–44.
26. Herrmann C. International experiences with the Hospital Anxiety and Depression Scale-A review of validation data and clinical results. *J Psychosom Res* 1997;42:17–41.
27. Stratford P. Assessing disability and change on individual patients: a report of a patient specific measure. *Phys Can* 1995;47:258–63.
28. Hudak P, Wright J. The characteristics of patient satisfaction measures. *Spine* 2000;25:3167–77.
29. Maughan E, Lewis J. Outcome measures in chronic low back pain. *Eur Spine J* 2010;19:1484–94.
30. Hay EM, Mullis R, Lewis M, et al. Comparison of physical treatments versus a brief pain-management programme for back pain in primary care: a randomised clinical trial in physiotherapy practice. *Lancet* 2005;365:2024–30.
31. Nigg B, Davis E, Lindsay D, et al. The effectiveness of an unstable sandal on low back pain and golf performance. *Clin J Sport Med* 2009;19:464–70.
32. Brumagne S, Janssens L, Knapen S, et al. Persons with recurrent low back pain exhibit a rigid postural control strategy. *Eur Spine J* 2008;17:1177–84.
33. Mok NW, Brauer SG, Hodges PW. Hip strategy for balance control in quiet standing is reduced in people with low back pain. *Spine* 2004;29:E107–E12.
34. Della Volpe R, Popa T, Ginanneschi F, et al. Changes in co-ordination of postural control during dynamic stance in chronic low back pain patients. *Gait Posture* 2006;24:349–55.
35. Tropp H, Askling C. Effects of ankle disc training on muscular strength and postural control. *Clin Biomech* 1988;3:88–91.
36. Fitzgerald GK, Axe MJ, Snyder-Mackler L. The efficacy of perturbation training in nonoperative anterior cruciate ligament rehabilitation programs for physically active individuals. *Phys Ther* 2000;80:128–40.
37. Nigg BM, Hintzen S, Ferber R. Effect of an unstable shoe construct on lower extremity gait characteristics. *Clin Biomech* 2006;21:82–8.
38. Hodges P, Richardson C. Delayed postural contraction of transversus abdominis in low back pain associated with movement of the lower limb. *J Spinal Dis* 1998;11:46–56.
39. Hodges P, Richardson C. Altered trunk muscle recruitment in people with low back pain with upper limb movement at different speeds. *Arch Phys Med Rehab* 1999;80:1005–12.
40. Deyo R, Battie M, Beurskens A, et al. Outcome measures for low back pain research: a proposal for standardised use. *Spine* 1998;23:2003–13.
41. Bombardier C. Outcome assessments in the evaluation of treatment of spinal disorders. *Spine* 2000;25:3100–03.
42. Dunn KM, Jordan K, Croft PR. Characterizing the course of low back pain: a latent class analysis. *Am J Epidemiol* 2006;163:754–61.
43. Linton S. A review of psychological risk factors in back and neck pain. *Spine* 2000;25:1148–56.
44. Davis CE. *Regression to the Mean*. Wiley Encyclopedia of Clinical Trials. Hoboken, NJ: John Wiley & Sons Inc.; 2007.
45. Stewart-Williams S, Podd J. The placebo effect: dissolving the expectancy versus conditioning debate. *Psychol Bull* 2004;130:324–40.
46. Shiv B, Carmon Z, Ariely D. Placebo effects of marketing actions: consumers may get what they pay for. *J Marketing Res* 2005;42:383–93.
47. Moseley GL. Do training diaries affect and reflect adherence to home programs? *Arthritis Care Res* 2006;55:662–64.